



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,213	02/08/2000	Mark G. Schrom	16724-108	2262

36029 7590 04/23/2004

DOCKET CLERK, DM/ANSI
P.O. BOX 802432
DALLAS, TX 75380

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 04/23/2004

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,213

Applicant(s)

SCHROM ET AL.

Examiner

George R Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-56, 62-64 and 66-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-56, 62-64 and 66-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>25</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3762

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 43, 44, 52, 53, 62, 63, 67, 68, 69, 71, 72, 73, 75, 76, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz. The recitation of “electroplated”, “electroplating material” or “electroplating process” in the claims are more like method steps directed to how the links are produced rather than structural limitations and Iwaszkiewicz’s links, 20, are structurally equivalent to the claimed links (for claims 73 and 77, see the alternative 103 rejection below). In addition, Iwaszkiewicz shows the use of conductor 19 extending substantially the length of the body member and connecting to electrode 11 through two links, 20.

Art Unit: 3762

Iwaszkiewicz discloses the claimed invention except for the duplication and connection of the conductors (second), tunnels/openings/removals (third and fourth tunnels/openings/removals connected to the second conductor), links (third and fourth links in third and fourth tunnels/openings/removals), and electrode (second electrode connected to third and fourth link) to provide a second band distal electrode positioned proximate the outer surface of the body member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Iwaszkiewicz, with a second duplicate connection of conductors, tunnels, links, and electrode to provide a second band distal electrode positioned proximate the outer surface of the body member since it was known in the art that medical leads use more than one electrode to easily provide stimulation/therapy to different and close locations in the body of a patient at the same time with only one lead. In addition, it has been held that duplication of parts is obvious to one having ordinary skill in the art at the time the invention was made (In re Harza, 124 USPQ 378).

In addition, for claims 63, 69, 71, 76 and 78, Iwaszkiewicz discloses the claimed invention except for the first and second conductors spiraled along substantially the length of the body member about the same distance from a longitudinal axis of the body member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead with a second electrode as taught by Iwaszkiewicz, with the first and second conductors spiraled along substantially the length of the body member about the same distance from a longitudinal axis of the body member since it was known in the art that medical leads providing a second electrode use the first and second conductors spiraled along substantially the length of the body member about the same distance from a longitudinal axis of the body member

Art Unit: 3762

to provide a second duplicate electrode on the distal end of the lead body to provide additional therapy to the body with the same lead and use conductors spiraled about the same distance from a longitudinal axis of the body member to provide a lumen for insertion of additional elements and/or provides additional rigidity/flexibility to assist in insertion and adaptation of the lead.

For claims 73 and 77, in the alternative, Iwaszkiewicz discloses the claimed invention except for the conductive links being electroplating material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the conductive links in the medical lead as taught by Iwaszkiewicz, with electroplating material as the conductive links since it was known in the art that medical leads use electroplating material as conductive links to provide a lightweight, flexible material that is easily produced to make a conductive link for electrical connection between elements.

Claims 54, 66, and 70 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iwaszkiewicz. Iwaszkiewicz has the width of the electrode, 11, as 0.3 mm (2.3 mm OD - 2.0 mm ID) and therefore is a thin film electrode. In addition, the first and second segments of the electrode are the proximal and distal segments of the electrode. Also, the conductors are shown spiraled at an angle of about 80 degrees (claims 66 and 70, for claim 70, the 103 rejection above provides the conductors being located the same distance from the longitudinal axis).

In the alternative, Iwaszkiewicz's discloses the claimed invention except for the thin film electrode and conductors spiraled at about 10 to about 80 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead

Art Unit: 3762

as taught by Iwaszkiewicz, with the thin film electrode and conductors spiraled at about 10 to about 80 degrees since it was known in the art that medical leads use thin film electrodes to provide a small, flexible lead that is easily inserted into the body and since it was known that medical leads use conductors spiraled from about 10 to about 80 degrees to provide greater or lesser torque and flexibility to the leads.

Claims 45-50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz et al. For claims 48, 49, 50, Iwaszkiewicz discloses a thin film electrode with the conductor being stainless steel or MP35N and spiraled at an angle of about 80 degrees. In the alternative, see the 103 rejection given in the preceding paragraph.

Iwaszkiewicz discloses the claimed invention except for the first conductor being embedded in the annular wall (claims 45 and 56), the outer diameter of the lead being about 2 French and internal diameter being 0.012 inch (claim 46), and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high (claim 47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught Iwaszkiewicz, with the conductor being embedded in the annular wall, an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch, and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, since it was known in the art that leads have: conductors embedded in the annular wall to ensure stability of the conductors and overall strength of the lead; an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch to allow the lead to be unobtrusively placed in small areas of the body and to prevent tissue damage and irritation; and

Art Unit: 3762

the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high to provide a small diameter lead with flexibility in particular directions.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Iwaszkiewicz with the outer diameter being about 2 French and internal diameter being 0.012 inch and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, because Applicant has not disclosed that the outer diameter being about 2 French and internal diameter being 0.012 inch and the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.002 inch high, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode lead having circular conductors in a helical pitch as taught by Iwaszkiewicz because it will provide a small body implantable flexible lead that is easily and quickly produced.

Therefore, it would have been an obvious matter of design choice to modify Iwaszkiewicz to obtain the invention as specified in the claim(s).

Claims 51, 64, 74, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz in view of Willis, 5433742 (or Gotthardt et al, 5016646).

Iwaszkiewicz discloses the claimed invention except for the conductive links being a conductive epoxy. Willis (or Gotthardt) teaches that it is known to use a conductive epoxy to provide a good mechanical and electrical connection between the conductors and electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical lead as taught by Iwaszkiewicz, with the conductive links being a

Art Unit: 3762

conductive epoxy as taught by Willis (or Gotthardt), since such a modification would provide a medical lead with conductive links being a conductive epoxy to provide a good mechanical and electrical connection between the conductor and electrode.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaszkiewicz.

Iwaszkiewicz discloses a thin film electrode. In the alternative, see the 103 rejection above.

Iwaszkiewicz discloses the claimed invention but does not disclose expressly the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the medical lead as taught by Iwaszkiewicz, with the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns because Applicant has not disclosed that the thin film electrode comprising a first layer of titanium, chromium, etc of 5 microns and a second layer of gold, platinum, etc of about 500 angstroms to about 50 microns provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode as taught by Iwaszkiewicz, because it provides a thin, small electrode that is easily inserted into the body.

Therefore, it would have been an obvious matter of design choice to modify Iwaszkiewicz to obtain the invention as specified in the claim(s).

Art Unit: 3762

Response to Arguments

Applicant's arguments filed 1/29/04 have been fully considered but they are not persuasive. The argument that the duplication of parts or obviousness rejection using the Iwaszkiewicz reference is not obvious with respect to the Applicants invention is not persuasive. The previously cited prior art reference of Dahl et al (4559951), the Winkler reference (5417208) recently cited in the IDS, and the newly cited Vaiani et al (5374285) reference are three teachings of many that show the use of a duplicate electrode for a second distal band electrode to provide additional therapy to the body using only a single lead and show the conductors being spiraled along substantially the entire body member at the same distance from a longitudinal axis of the body member (the references additionally show spiraling of the conductors at approximately 45-80 degrees). All three are teachings that show it is obvious to one having ordinary skill in the art to provide a duplicate electrode for a second electrode. The arguments that multiple conductors would make lead construction more complicated and increase the cross section significantly are not persuasive since the Dahl, Winkler, and Vaiani reference all show this construction being performed, do not provide an increased cross-section since the conductors are all spiraled at the same distance from the longitudinal axis, and since the difficulty of the lead construction is not being claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3762

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE
April 18, 2004

GEORGE R. EVANISKO
PRIMARY EXAMINER

4/12/4